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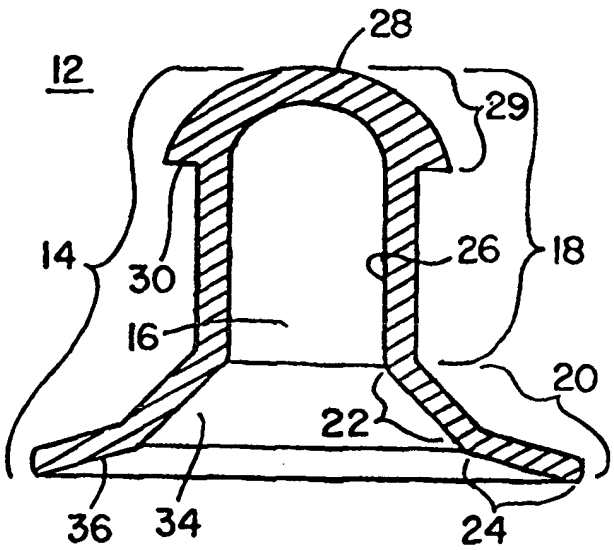
(54) Title: FEMALE URINARY INCONTINENCE DEVICE

(57) Abstract

A device for alleviating female urinary incontinence comprising an at least partially deformable device body having a hand gripping portion and a body contacting surface. The device body defines a chamber which is sized and shaped to close the user's meatus when the device is in place on the user's body. When the device is positioned on a user's body, deformation of the device body provides a vacuum within the chamber which is sufficient to hold the device onto the user's body and to create a seal between the device and the user's body to prevent urinary flow beyond the device.



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FEMALE URINARY INCONTINENCE DEVICE

Field of the Invention

The invention relates generally to a device for alleviating female urinary incontinence and more specifically to a device which constricts the meatus urinarius to alleviate female urinary incontinence.

Background of the Invention

Female urinary incontinence is a substantial problem throughout the world and can result from a variety of physical or mental dysfunctions. Neurogenic bladder dysfunction, trauma to the urethra or bladder neck, and injuries sustained during childbirth can all cause urinary incontinence in women. As well as being a medical problem, the condition can be socially embarrassing to women afflicted with the problem.

A variety of devices have been suggested to alleviate female urinary incontinence. Many of the suggested medical devices have internal components such as catheters, balloons and pessaries which pass into either the urethra or vagina and must remain positioned within the user's body when the device is in use. Several disadvantages exist with these internal devices. The internal components may be a source of irritation to the body or result in infection or other unwanted body reactions. Moreover, such devices as are known can be uncomfortable to wear, inconvenient to use, and expensive.

Therefore, it is important to provide a device that alleviates female urinary incontinence, does not create a high risk of body infection, can be comfortably worn, is easily applied and removed, and is inexpensive to provide.

The present invention provides the aforementioned desirable characteristics while avoiding the undesirable characteristics of prior art devices.

Summary of the Invention

The invention relates to a device for alleviating female urinary incontinence. The device has a resilient and at least partially deformable body. The body of the device has a hand gripping portion and an encircling flange. The encircling flange has a body contacting surface which acts to seal the device to the user's body. The device's body also defines a chamber which is sized and shaped to contact and constrict the user's meatus when the device is in place on the user's body. The device is held in place by a differential in air pressure. When the device is positioned on a user's body, a partial compression of the device's body provides a vacuum within the chamber of the device which is sufficient to maintain the device in position on the user's body and to create a seal between the device and the user's body to prevent urinary flow beyond the device.

The invention also relates to a method for alleviating female urinary incontinence. The method includes the steps of applying a urinary incontinence device having an internal chamber, a hand gripping portion, and an encircling flange with a body contacting surface over the orifice of the user's urethra; employing air pressure below ambient atmospheric air pressure to maintain the device in position on the user's body; and removing the device to allow voiding when desired. Once the device is in place, the walls of the chamber substantially close the meatus of the user's body thereby alleviating urinary incontinence. In one embodiment, the device is applied to the user's body by resiliently compressing the device, contacting the device's body contacting surface with the user's body, and allowing the device to resiliently return towards its original configuration.

Brief Description of the Drawings

This invention is pointed out with particularity in the appended claims. The above and further advantages of this invention may be better understood by referring to the following description taken in conjunction with the accompanying drawings, in which:

Fig. 1 is a perspective view of an embodiment of a female urinary incontinence device having a circular body defining a chamber;

Fig. 2 is a cross-sectional view of the device of Fig. 1 taken through line 2-2' of Fig. 1;

Fig. 3 is a bottom view of the device of Fig. 1; and

Fig. 4 is a cross-sectional view taken through line 2-2' of Fig. 1 of the device of Fig. 1 when in place on the body of the user.

Detailed Description of the Invention

In broad overview and referring to Figs. 1-3, an embodiment of a female urinary incontinence device 12 of the invention, as shown in perspective view, cross-sectional view and bottom view in the respective Figures, includes a device body 14. Device body 14 defines a chamber 16 and has a vacuum producing portion 18 and a body contacting portion 20. The body contacting portion 20 comprises an intermediate frustoconical portion 22 and an outer encircling flange 24. The chamber 16 extends from the top of the device to the tip of the flange 24.

Figs. 1-3 show a vacuum producing portion 18 having a circular shape with a substantially vertical cylindrical sidewall 26 centered around the central axis of the device, a rounded outer endwall 28, and a finger gripping portion 29 with a finger gripping ledge 30.

In the preferred embodiment, device 12 is integrally formed by conventional molding. Also, in the preferred embodiment, device 12 is composed of an FDA approved material. While device 12 is typically a unitary part formed out of one piece of material, it may be formed out of multiple pieces of materials joined together. The

vacuum producing portion 18 must be at least partially compressible in order to produce at least a partial vacuum in the chamber 16 sufficient to seal the device 12 to the user's body by a differential in air pressure between the air within the chamber 16 and the atmospheric air pressure. Production of the vacuum will be discussed in more detail below.

The thickness of the device body 14 is designed such that cylindrical sidewall 26 is thicker and more resistant to deformation or collapse by atmospheric pressure than is the flange 24 which tapers in thickness from the intermediate frustoconical portion 22 to the edge of the device body 14. In this embodiment both sidewall 26 and flange 24 can be formed of an FDA approved medical material. When the device 12 is in use, the difference in wall thickness prevents the device 12 from collapsing on itself, yet still allows the flange 24 to move towards the user's body.

Fig. 4 shows the urinary incontinence device 12 of Figs. 1-3 in use. As shown in Fig. 4, the flange 24 can be deformed towards or closely contact the user's body at the planar area of the user's body surrounding the meatus urinarius or urethra orifice. In one embodiment, the device body 14 can draw a portion of the orifice of the urethra 32 into contact with the flange 24 and intermediate frustoconical portion 22. Drawing a portion of the orifice of the urethra 32 into contact with the device body 14 acts to close the user's meatus to urine flow, to maintain the device 12 in position on the user's body, and to form a good seal between the user's body and the device 12 at flange 24.

In a preferred embodiment, when the device 12 is in use, the user's meatus is closed by a gentle compression of the area surrounding the meatus. This compression forms a closure which is maintained in position by the vacuum produced in the vacuum producing portion 18. Any structure that externally closes the meatus to urine flow, yet allows for comfort in use, can provide the advantages of this invention. These advantages can be obtained by the device 12 being applied solely externally of the user's body without any part of the device body 14 entering the user's body.

Figs. 1 and 2 show a finger gripping ledge 30 attached to the outer endwall 28. However, it is not necessary for device 12 to comprise finger gripping ledge 30. The

finger gripping ledge 30 is important for placement particularly in older patients. Any configuration of device body 14 which is designed to allow the user to grip the device 12 by the user's fingers thereby allowing the user to position the device 12 on the user's body and to remove the device 12 from the user's body by the user's fingers is acceptable. In other embodiments, the finger gripping portion 29 can be simply the outer surface of the cylindrical outer sidewall 26 that surrounds the chamber 16. Thus, although Figs. 1-3 show device 12 having a cylindrical sidewall 26, rounded outer endwall 28, intermediate frustoconical portion 22, and outer encircling flange 24, the shape of device 12 can vary greatly.

The purpose of the intermediate frustoconical section 22 is to provide closure of the user's meatus. Typically, the angle of the body contacting surface 34 of the intermediate frustoconical portion 22 with the body contacting surface 36 of the outer encircling flange 24 is obtuse to enhance the closure of the meatus. The body contacting surface 34 of the intermediate frustoconical portion 22 defines the lower portion of chamber 16 and closes the meatus by pressing on the meatus.

Attached to the intermediate frustoconical portion 22 is the outer encircling flange 24 discussed above. In the preferred embodiment shown in Figs. 1-3, the outer encircling flange 24 has a body contacting surface 36 which forms a continuous ring about the meatus or opening of the user's urethra. However, other portions of the device 12, such as the vacuum producing portion 18, can be square, round, oblong, bulbous, or any shape desired. Outer endwall 28 may be flat rather than rounded. In all embodiments the chamber 16 has adequate volume to allow a vacuum to be formed within the chamber 16 sufficient to hold the device 12 onto the user's body.

The device 12 may come in many different sizes. However, consistent with normal anatomy of females in the United States, in the preferred embodiment, the body contacting portion 20 has an outer diameter preferably in the range of 2.3 to 3.4 centimeters with approximately 3.4 centimeters being preferred. The range of 2.3 to 3.4 centimeters in outer diameter is important for proper positioning of the device on the user's body and for maintaining the device 12 in place on the user's body. In the

embodiments where the flange 24 has an encircling shape such as oval, square, oblong or triangular, the flange 24 can have a maximum width of approximately 3.4 centimeters. The outer encircling flange 24 has an inner diameter preferably in the range of 1.0 centimeter to 2.5 centimeters with approximately 1.5 centimeters being preferred. The device 12 has a height preferably in the range of 1.0 to 3.0 centimeters with approximately 2.0 centimeters being preferred. The height of device 12 can vary greatly, but by maintaining the height of device 12 between approximately 1.0 and 3.0 centimeters, the user can wear the device without discomfort and position the device easily. The height is preferably no more than approximately 3.0 centimeters to allow ease of use. In addition, when the height is maintained between approximately 1.0 and 3.0 centimeters, once the device is positioned on the user, it is covered by the vaginal labia and is resistant to dislodging by garments worn by the user.

In the preferred embodiment, the device 12 is integrally formed of elastomeric material.

Figs. 1-3 show an embodiment of the incontinence device 12 that is symmetrical about a central axis. However, the device 12 need not be symmetrical in all embodiments.

Fig. 4 shows the placement of the female urinary incontinence device 12 of Figs. 1-3 when in use. The user positions the flange 24 so that it lies substantially just within the user's labia on a substantially planar area surrounding the meatus. This spacing helps the user to locate and place the device 12 in position. When in position, the device 12 pulls the mucosa about the meatus into direct contact with the body contacting surfaces 34 and 36 of the intermediate frustoconical portion 22 and encircling flange 24 respectively. The body contacting surfaces 34 and 36 press against the mucosa surrounding the meatus to close the meatus and prevent urine outflow. Positioning the mucosa below the flange 24 aids in centering and maintaining the device 12 in position on the user's body.

Using a female urinary incontinence device 12 made of a resilient and partially deformable material is accomplished according to the following method. The user

inwardly deforms the device body 14, applies the device body 14 over the orifice of the urethra and releases the device body 14 to allow the device body 14 to expand toward its original shape as shown in Fig. 2. As the device body 14 expands toward its original shape, a vacuum will be created within the inner chamber 16. The vacuum causes the outside atmospheric pressure to push against the flange 24 and intermediate frustoconical portion 22 and maintain the device 12 in good sealing engagement with the user's body. The air pressure difference compresses the mucosa or tissue immediately surrounding the meatus and forms a seal between the user's body and the device 12 at surfaces 34 and 36. The difference in pressure between the inside of the device 12 and the atmosphere can vary greatly. The difference in pressure is controlled in part by the amount the user depresses the chamber 16 before allowing the device body 14 to resiliently return toward its normal configuration as shown in Fig. 2. In some cases, the device body 14 does not fully return to its normal configuration after being compressed and applied to the user. However, in all cases, at least a partial vacuum remains inside the chamber 16. As well as containing a vacuum, the interior chamber 16 can act as a reservoir and store leakage that may occur while the device 12 is in place. In most embodiments of the device 12 leakage does not normally occur.

The difference in air pressure between the inside of the device 12 and the atmosphere is difficult to ascertain. In the preferred embodiment, since the device body's walls are resiliently deformable, the difference in pressure is created by the depression of the device body 14 and the expansion of the device body 14 towards its original shape after being applied to the user's body. The difference in air pressure may vary between applications even when the same device is used because the difference in air pressure depends on how the device is applied and how much the user depresses the device body 14. Surprisingly, it has been found that even with small devices designed and applied following the method of this invention, a sufficient difference in air pressure is created to maintain the device in position on the user's body and avoid urine flow.

Thus, a female user can alleviate urinary incontinence, such as stress incontinence, by applying the device 12 over the urethral orifice using the labia spacing

to help position the device. To apply the device 12, prior to contacting the device body 14 with the user's body, the user resiliently depresses the device body 14 at the finger gripping portion 29. Once the device body 14 is depressed, the user brings the encircling flange 24 into contact with the mucosa surrounding the orifice of the urethra. With the device body 14 the user then applies slight pressure on the mucosa surrounding the orifice of the urethra. The user then releases the device body 14 causing a vacuum to be produced within the device. The vacuum provides the difference in air pressure which causes the atmosphere to press on the outside of the flange 24 and frustoconical portion 22. This pressure maintains the device 12 in place on the user's body and closes the user's meatus as shown in Fig. 4. When desired, the user can release the vacuum and easily remove the device 12 to allow voiding. The user may release the vacuum before removing the device 12 by slightly depressing the finger gripping portion 29. In some cases, the user can merely pull the device 12 off of the mucosa. The device 12 is comfortable to wear, can be easily applied by a majority of patients and has been found to prevent urinary leakage and thus alleviate urinary incontinence including stress incontinence in women.

In other embodiments, the device 12 of this invention can be sterilized prior to use to reduce the risk of infection or irritation to the user's skin. As the device is external to the user's body when in use and does not have any component passing within the urethra, the device does not require sterilization prior to use.

It has been found that devices of the type described above can be used for long periods of time and maintain in contact with and sealed to the user's skin for periods of 2 to 6 hours or more in some cases.

Having described preferred embodiments of the invention, it will now become apparent to one of skill in the art that other embodiments incorporating the concepts may be used. The particular materials, integral nature, and geometric configuration of the devices of this invention can vary greatly. In all embodiments, a difference in air pressure between the device's chamber 16 and the atmosphere is essential to provide a seal between the device and the user's body. The seal acts in conjunction with a

mechanical closure of the meatus to alleviate urinary incontinence. The seal formed between the flange 24, intermediate frustoconical portion 22 and the user's body by the difference in air pressure is sufficiently strong to withstand and to prevent urinary flow out of the device over long periods of time at urinary pressures normally encountered at the urethral orifice. It is felt, therefore, that these embodiments should not be limited to disclosed embodiments but rather should be limited only by the spirit and scope of the following claims.

CLAIMS

What is claimed is:

1. A device for alleviating female urinary incontinence comprising:

a resilient and at least partially deformable device body having a hand gripping portion,

said device body defining a chamber there within sized to allow for reciprocal resilient deformation of said device body to provide a vacuum therein to hold said device on a user's body and close the meatus of said user's body,

said device body defining an encircling flange having a body contacting surface to act as a sealing surface with said user's body.

3. The device of claim 1 wherein said encircling flange has an outer diameter between about 2.3 and about 3.4 centimeters.

4. The device of claim 1 wherein said encircling flange has an outer diameter of about 3 centimeters.

5. The device of claim 1 wherein said chamber defines a central axis passing from a top of said device body to a bottom of said device body, with said bottom being defined by said encircling flange, said top to bottom having a height of about 2 centimeters.

6. The device of claim 1 wherein said device is integrally formed of a resilient material which allows ease of application to said user's body by deforming said chamber of said device body, applying said device to said user's body about the orifice of a urethra and releasing said deforming pressure to define an air pressure difference between said chamber and the atmosphere sufficient to seal said encircling flange to said user's body and to prevent liquid flow therethrough at normal pressures encountered in urinary fluids expressed by the body,

said device further defining a meatus constricting surface to close said meatus when said device is applied with said pressure difference acting to position said device.

7. A method for alleviating urinary incontinence of a female user comprising the steps of:

applying a urinary incontinence device having an internal chamber over a urethra outer body orifice of a user's body, said device defining a hand gripping portion and an encircling flange having a body contacting surface area which aids in sealing said device to said user's body;

employing air pressure below ambient atmospheric air pressure to maintain said device in place; and

removing said device to allow voiding when desired.

8. The method of claim 7 wherein said air pressure acts to compress and seal the meatus to urinary flow and wherein the step of applying a urinary incontinence device to said user's body further comprises the steps of:

resiliently compressing said device;

contacting said body contacting surface area with said user's body;

positioning a central axis of said device over said urethra outer body orifice; and

allowing said device to resiliently return towards its original configuration.

9. In a method of preventing unwanted urinary flow from the body of a female user, the method comprising:

applying a urinary incontinence device over the orifice of the urethra and

maintaining said incontinence device in place on the body of the user by the use of air pressure to prevent urinary flow beyond said incontinence device.

10. In a method of alleviation of urinary incontinence, wherein a hand applied device is used to prevent unwanted urinary flow, the improvement comprising:

using a hand applied and removable device mounted externally of the body to close the meatus of the body to urinary flow, and

removing said device from the body to allow the meatus to return to its opened natural state and permit urinary flow when desired.

11. A device for alleviating urinary incontinence when attached to a user's body, while minimizing infection of the user by avoiding the use of components of said device passing into or through the urethra of said user, said device having an interior surface and an exterior surface and defining an interior chamber for establishing a pressure differential between said device and the atmosphere to aid in maintaining said device in position attached to said user's body, said device comprising:

a hand gripping portion for use in mounting said device over the urethra external orifice of said user's body,

a meatus compressing and closure surface, and

an encircling flange having a body contacting surface to act as a sealing surface with the user's body, said encircling flange being constructed and arranged to surround said urethral external orifice.

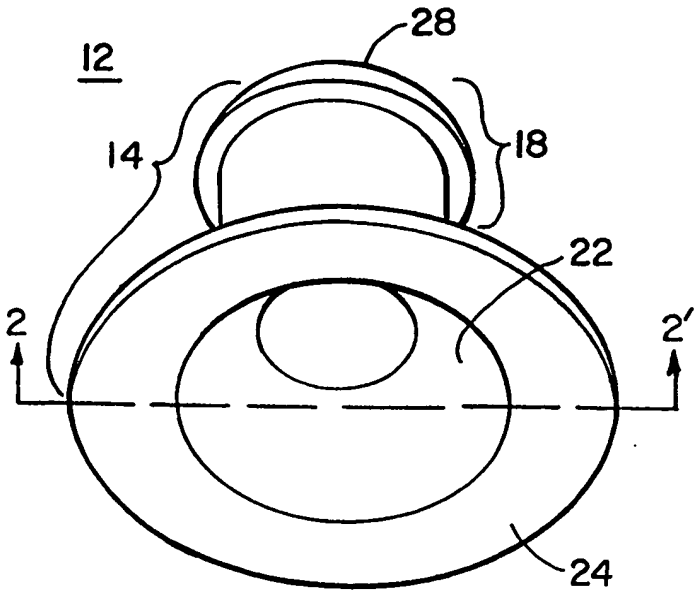

FIG. 1

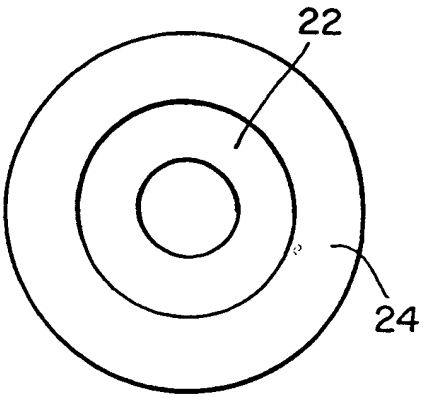

FIG. 3

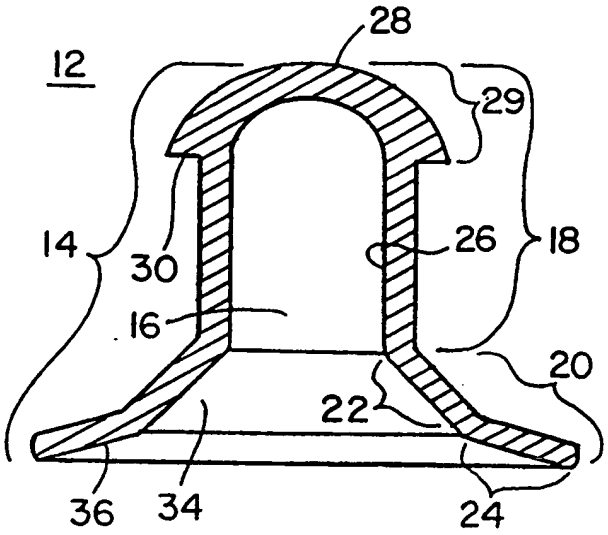

FIG. 2

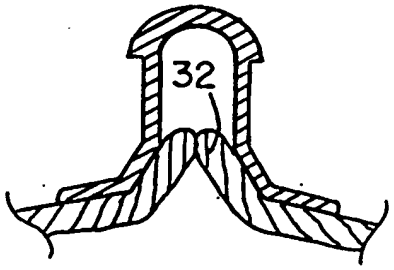

FIG. 4

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 96/07517

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB,A,2 193 438 (HOLLISTER INC) 10 February 1988 see abstract; figures see page 2, line 61 - line 69 see page 3, line 68 - line 72 ---	1,6,11
A	GB,A,1 467 144 (HOLLISTER INC) 16 March 1977 see page 2, line 34 - page 3, line 20; figures ---	1,3,4,6, 11
A	WO,A,90 08561 (RAWLINSON BRIAN ;SASSON JEAN P (US); KENNEDY ROBERT B (US); RAWLIN) 9 August 1990 see page 5, line 13 - line 31; figures --- -/--	1,3,4,11

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
16 October 1996	22.10.96

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Inter. nal Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE,A,36 33 824 (NEUHAUSER JOHANN DIPL ING DR I) 14 April 1988 see column 1, line 62 - line 65; figures	1,6,11
A	US,A,3 958 564 (LANGGUTH ARTHUR F) 25 May 1976	
A	FR,A,1 223 353 (TAJAN) 16 June 1960	

INTERNATIONAL SEARCH REPORT

rnational application No.

PCT/US96/07517

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 7-10
because they relate to subject matter not required to be searched by this Authority, namely:
Please seee Rule 39.1(iv) PCT.

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

Inter nal Application No
PCT/US 96/07517

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB-A-2193438	10-02-88	NONE	
GB-A-1467144	16-03-77	NONE	
WO-A-9008561	09-08-90	EP-A- 0411085 JP-T- 4500471	06-02-91 30-01-92
DE-A-3633824	14-04-88	NONE	
US-A-3958564	25-05-76	NONE	
FR-A-1223353		NONE	